DATA EVALUATION REPORT

POLY(IMINOIMIDOCARBONYLIMINOIMIDOCARBONYLIMINOHEXAMETHYLENE HYDROCHLORIDE (PHMB IN BAQUACIL/VANTOCIL IB/COSMOCIL CQ/REPUTEX FORMULATIONS)

STUDY TYPE: Enforcement Analytical Method (OPPTS 830.1800)

MRID 44881501; DP BARCODE: D258249

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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Prepared by
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Disclaimer

This Data Evaluation Report may have been altered by the Antimicrobials Division subsequent to signing by Oak Ridge National Laboratory personnel.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

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DATA EVALUATION REPORT

STUDY TYPE: Enforcement Analytical Method (OPPTS 830.1800)

CASE NO.: 021125

P.C. CODE: 111801

DP BARCODE: D258249

SUBMISSION: S566146

MRID NO.: 44881501

TEST MATERIAL: PHMB in Baquacil/Vantocil IB/Cosmocil CQ/Reputex formulations (a.i. Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene hydrochloride, 20%)

SYNONYMS: Poly(hexamethylenebiguanide)hydrochloride, PHMB (EPA Reg. No. 10182-45), Baquacil (EPA Reg. No. 10182-19), Vantocil IB, Cosmocil CQ, Reputex, Baquacil® Swimming Pool Sanitizer and Algistat

STUDY/REPORT NUMBER: none assigned

SPONSOR: Zeneca Inc., 1800 Concord Pike, Wilmington, DE 19850-5457

TESTING FACILITY: Zeneca Inc., 1800 Concord Pike, Wilmington, DE 19850-5457

TITLE OF REPORT: Quantification of PHMB in Baquacil/Vantocil IB/Cosmocil CQ/Reputex Formulations

AUTHOR: Rajan, J.S.

REPORT ISSUED: July 23, 1999

EXECUTIVE SUMMARY: The enforcement analytical method of PHMB (EPA Reg. No. 10182-45) is addressed in MRID 44881501. PHMB, an active ingredient in Baquacil/Vantocil IB/Cosmocil CQ/Reputex Formulations, is a swimming pool sanitizer. An HPLC method with detection at 220

nm is used to determine the content of the active ingredient in the formulations. A calibration curve of the peak area versus concentration of the calibration standards was prescribed.

Classification of studies: **Acceptable**

COMPLIANCE: A signed and dated Data Confidentiality statement was provided. The signed GLP compliance statement indicated that the submission was not conducted or required to be conducted under GLP Guidelines. A Quality Assurance statement was not included.

A. ENFORCEMENT ANALYTICAL METHOD (OPPTS 830.1800)

The enforcement analytical method is based on analysis of PHMB by using HPLC. The instrument used is a Beckman 110B HPLC pump or equivalent, LDC/Molton Roy SpectroMonitor 3000 variable wavelength UV detector or equivalent, and ICI LC 1600 autosampler or equivalent. The parameters for HPLC are as follows: The column is Zorbax PSM 60, 6 μm, 250 mm x 6.2 mm, ex. MAC-MOD, two columns connected in a series; the mobile phase and eluent is isocratic 0.02 M HCl + 0.08 m NH_4Cl in 55:45 methanol:water; the flow rate is 0.5 mL/minute; the injection voulme is 50 μL; run time is 45 minutes at ambient temperature; the detector settings are: a wavelength of 220 nm, output 1 V, range 0.1 AUFS. Standard solutions were prepared with 80, 100, or 120 mg analytical grade PHMB in the mobile phase to obtain 0.8, 1.0, or 1.2 mg/mL stock solutions. The test sample was prepared by weighing 500 mg of sample solution into 100 mL of the mobile phase; the sample is filtered with 0.45 μm Millex HV syringe filter if necessary. The standard solutions and the sample solution were injected in sequence. PHMB eluted at approximately 18-25 minutes. The determination of PHMB concentration in sample solution was by the following equation:

$$\text{Concentration of PHMB (\%)} = \frac{\text{peak area of sample} \times \text{conc. of standard} \times 100\text{ mL} \times 100}{\text{peak area of standard weight of sample (mg)}}$$

B. DISCUSSION

In MRID 44881501, the enforcement analytical method of PHMB (EPA Reg. No. 10182-45) in Baquacil/Vantocil IB/Cosmocil CQ/Reputex Formulations was described. An HPLC method was used to determine the content of the active ingredient in the formulation. A calibration curve of the peak area versus concentration of the calibration standards was provided; linear regression was used to calculate sample concentrations.

Classification of studies: **Acceptable**

C. STUDY DEFICIENCIES

Minor deficiencies include that GLP was not followed and a Quality Assurance statement was not included.